IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
MCALLEN DIVISION

ACUTE CARE AMBULANCE SERVICE, LLC,	§	
	§	
Plaintiff,	§	
	§	
v.	§	
	§	**CIVIL ACTION NO. 7:20-cv-00217**
ALEX M. AZAR II, Secretary, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,	§	
	§	
Defendant.	§	

MEMORANDUM OF LAW
IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

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TO THE HONORABLE UNITED STATES DISTRICT COURT JUDGE:

Acute Care Ambulance, L.L.C. (the "Plaintiff" or "Acute Care") files this its Memorandum of Law in Support of Motion for Preliminary Injunction, pursuant to Fed. R. Civ. P. 65, against Alex M. Azar II, Secretary of Health & Human Services for the U.S. Department of Health & Human Services (the "Defendant" or "HHS"). Due to exigent circumstances, Plaintiff files this motion and relief is requested by October 9, 2020.

NATURE AND STAGE OF PROCEEDING

Plaintiff seeks a preliminary injunction that requires Defendant to *temporarily* enjoin a Medicare payment suspension imposed during the COVID-19 pandemic and national emergency, and release all suspended payments, until the national emergency is lifted or Defendant otherwise gives notice and an opportunity for a hearing on the adverse action in conformance with Due Process of Law. The government's ill-advised Medicare payment suspension during the COVID-19 crisis will irreparably harm Plaintiff by destroying its business and forcing its closure, and it jeopardizes the health and safety of the Plaintiff's patients and violates their Due Process right (consistent with principles of equal protection) to access essential healthcare services.

ISSUES AND LEGAL STANDARD

A preliminary injunction is to preserve the *status quo* and prevent irreparable harm. To be entitled to a preliminary injunction, a movant must show (1) a likelihood of success on the merits; (2) a substantial threat of irreparable injury to Plaintiff if an injunction is not granted; (3) that the threatened injury to Plaintiff outweighs the threatened harm the injunction may do to Defendant; and (4) that granting the preliminary injunction will not disserve the public interest. *Canal Authority of State of Fla. v. Callaway*, 489 F.2d 567, 572 (5th Cir. 1974).

SUMMARY OF THE ARGUMENT

Plaintiff, a Medicare certified ambulance supplier, seeks to *temporarily* enjoin HHS's Medicare payment suspension during the COVID-19 emergency or until a hearing is provided on the adverse action in accordance with Due Process of Law. The suspension will irreparably harm the supplier by forcing it out of business and into bankruptcy, and it jeopardizes the health and safety of its patients by disrupting services and requiring that they obtain them elsewhere in the greater-Houston area, a "hotspot" of the COVID-19 outbreak. HHS violates Due Process of Law and the Fifth Amendment of the U.S. Constitution by imposing the Medicare payment suspension that confiscates Plaintiff's earned Medicare payments but provides no appeal or right to a hearing to challenge the sanction. [1]

Acute Care provides ambulance services to Medicare beneficiaries when the use of other methods of transportation is contraindicated. Essentially, this requires that the ambulance supplier show that patients' health would be jeopardized by use of any other mode of transportation. Typically, Medicare covers *emergency* ambulance transportation when a patient experience sudden medical emergency and it endangers his or her health. It also covers *nonemergency* transportation when medically necessary, and the patient has a written order from his or her physician that ambulance transportation is medically necessary.

[1] The Fifth Circuit's recent ruling in *Sahara Health Care, Inc. v. Azar*, No. 18-41120 (5th Cir. Sept. 18, 2020), has no application to the present case. In *Sahara*, the Court held that a home health agency could not complain about lacking due process because it had elected to wait for a required hearing but forgo "escalation." Also, the Court found that the case was distinguishable from the "unique circumstances" that justified the decision in *Am. Hosp. Ass'n v. Burwell*, 812 F.3d 183, 191 (D.C. Cir. 2016), where the D.C. Circuit Court had remarked in *dicta* that "nothing suggests that Congress intended escalation to serve as an adequate or exclusive remedy where, as here, a systemic failure causes virtually all appeals to be decided well after the statutory deadlines." The *Sahara* Court gave particular importance to the mandamus order to eliminate the backlog by the end of fiscal year 2022. The Court did not comment on the fact that HHS is not fully complying with the order, and that the backlog continues to grow. Nonetheless, *Sahara* has no application where HHS imposes a suspension that forces the healthcare supplier's closure, but denies it any appeal or right to a hearing to challenge the sanction.

Medicare beneficiaries rely upon Acute Care for nonemergency, scheduled repetitive ambulance services. Indeed, ambulance transportation is necessary to safely shuttle these patients to and from life-saving medical treatments. For example, patients that *must* rely on ambulance transport for dialysis will die if they do not receive this life saving treatment. Thus, Medicare covers ambulance transportation for a beneficiary who is receiving renal dialysis for treatment of end-stage renal disease (ESRD), from the beneficiary's home to the nearest facility that furnishes renal dialysis, including the return trip. *See* 42 C.F.R. § 410.40(e)(4). These transports are covered when the ambulance supplier furnishing the service obtains a written order from the beneficiary's attending physician certifying that the medical necessity requirements have been met. The physician's order must be dated no earlier than 60 days before the date the service is furnished.

On July 24, 2020, HHS imposed a Medicare payment suspension to withhold all earned payment for services rendered by the Medicare certified ambulance supplier. These payments will be applied toward a Medicare overpayment should one be subsequently determined by HHS. However, the government provided no appeal or right to hearing to dispute or contest the action. Plaintiff moves to temporarily enjoin HHS's "suspension" of its Medicare payments during the COVID-19 emergency or until the government provides a hearing on the adverse action in conformance with Due Process of Law.

The suspension will irreparably harm Plaintiff by forcing it out of business and into bankruptcy, and it jeopardizes the health and safety of the supplier's patients by disrupting their services and requiring that they obtain them elsewhere in the Rio Grande Valley, a "hot spot" of the COVID-19 outbreak. According to Ms. Jan Spears of MJS & Associates, an expert with 35 years of experience in Medicare ambulance operations, ambulance services for Plaintiff's patients may only be available through Plaintiff's supplier during the COVID-19 emergency, and if it is

forced to shut down, they may not be able to access essential healthcare under the Medicare program.

FACTUAL AND PROCEDURAL BACKGROUND

A. Medicare Home Care Provider

In the *Declaration Under Penalty of Perjury of Juan Carlos Rojas,* the ambulance supplier's President and owner that he has acted in that capacity at all times relevant to the issues underlying the lawsuit and that he has personal knowledge of the facts averred in his declaration. Exhibit 1, ¶ 1, 2. Acute Care is an ambulance supplier that is certified to participate in the Medicare program. It has been in operation in the Rio Grande Valley for over 9 years. It employs some 43 medics, drivers, and administrative staff. The supplier derives approximately 90% of its revenue from Medicare payments, and it has an estimated value of approximately $2.1 million. *Id*., at 3.

B. Medically Necessary Patient Care

Many of the ambulance transports are due to COVID-19. The ambulance supplier also has a diverse census of approximately 50 regular Medicare patients it transports on a scheduled and/or nonrepetitive basis. Exhibit 1, ¶ 4**.** Although it provides emergency transportation when a patient experiences a sudden medical emergency and it endangers his or her health, many patients rely on Acute Care for nonemergency, scheduled repetitive ambulance services. Medicare covers nonemergency transportation when medically necessary, and patients have a written order from their physicians that ambulance transportation is medically necessary. Ambulance services are necessary for medical transport for these patients to and from life-saving medical treatments. For example, patients that must rely on ambulance transport for dialysis will die if they do not receive this life-saving treatment. These transports are covered when the ambulance supplier furnishing

the service obtains a written order from the beneficiary's attending physician certifying that the medical necessity requirements have been met. The physician's order must be dated no earlier than 60 days before the date the service is furnished. *Id*.

C. Imposition of Medicare Payment Suspension

On July 24, 2020, Qlarant issued to Plaintiff a notice of suspension of Medicare payments that informed the hospice that CMS had suspended its Medicare payments effective that day. Exhibit 1, ¶ 5, Ex. A. The suspension took effect on July 22, 2020. The suspension was brought under 42 C.F.R. § 405.371(a)(2) and based upon a "credible allegation of fraud." [2] CMS based its decision to suspend upon its belief the ambulance supplier had failed to describe beneficiaries' symptoms at the time of transport and that any other means of transportation would be contraindicated. The list of sample claims indicates a *single incident* where a patient's transportation claim was denied due to deficient documentation. As a result, *all* Medicare payments owed to the ambulance company are being withheld pending resolution of the ongoing investigation. *Id*.

D. National Emergency for COVID-19 Pandemic

Unfortunately, the suspension action could not come at a worse time. President Donald Trump declared a national emergency over the COVID-19 outbreak on March 13, 2020. Exhibit 1, ¶ 7. Dr. Deborah Birx, White House Coronavirus Response Coordinator, has reported that U.S. deaths cause by COVID-19 may be catastrophic. She stated that Dr. Anthony Fauci, National Institute of Allergies and Infectious Diseases, has predicted U.S. deaths could range from 1.6 to 2.2 million in a worst-case scenario and projects 100,000 to 200,000 in a best-case scenario. To

[2] Critically, the provider has *not* been charged with fraud by the government; the allegation may be made by "any source." 42 C.F.R. § 405.370 (definitions). Unfortunately, healthcare is a competitive business and it is not uncommon for competing home health agencies or disgruntled employees to make such allegations to obtain a competitive advantage or as a means of personal vengeance.

date, there are now in excess of 200,000 COVID-19 related deaths. [3] The surge in confirmed coronavirus cases is having an overwhelming effect on our nation's hospitals. And it is having a cascading effect on ancillary providers, suppliers and practitioners as well, like Plaintiff's ambulance supplier. *Id*. Governor Gregg Abbott also declared a state of disaster in Texas due to COVID-19 on March 13, 2020. *Id*., at ¶ 8.

E. Coronavirus Spreading in Texas at an "Unacceptable Rate"

The surge in confirmed coronavirus cases is overwhelming south-Texas. Exhibit 1, ¶ 9. The Rio Grande Valley is particularly vulnerable to COVID-19 with more than 90% of its residents being Latinx and having one of the highest poverty rates in the State. Chronic health conditions abound. For example, the rate of diabetes is triple that of the national average. Also, it is chronically underfunded and underserved. Recently, Governor Abbott sent Navy teams to assist the area's hard-hit hospitals deal with the COVID-19 outbreak. The valley health community is so overrun by coronavirus that a field hospital or some other type of repurposed facility is now being built because current resources are failing in the fight to curb the COVID-19 outbreak. *Id*. And the problem is exacerbated by Hurricane Hanna striking the south-Texas coast on July 25, 2020. *Id*., at, ¶ 10. Dr. Ivan Melendez, Hidalgo County Health Authority, was quoted as saying that "The Rio Grande Valley has become the hotspot of a hotspot of a hotspot." *Id*., at ¶ 11.

F. Rio Grande Valley Ambulance Suppliers in Crisis

Ambulance companies in the Rio Grande Valley are in crisis due to the pandemic. Hospitals are in "divert" status – unable to accept new patients through ER. Exhibit 1, ¶ 12. Ambulances are being forced to wait in hospital parking sometimes for as long as 12 hours for bed to become available for their patients. In early-July 2020, the Texas Emergency Medical Task

[3] Reported by the Centers for Disease Control and Prevention as of September 21, 2020, at www.cdc.gov.

Force deployed "ambulance strike teams" to the Rio Grande Valley to help the local ambulance companies deal with such problems associated with the COVID-19 emergency. *Id*.

G. Rebuttal Statement Submitted for Suspension Exception

On August 3, 2020, a Rebuttal Statement was presented by Acute Care to Qlarant informing the UPIC that the Medicare suspension during the COVID-19 epidemic and national emergency that informed the contractor that the Medicare suspension during the COVID-19 national emergency was improper. Exhibit 1, ¶ 13, Ex. B. It explained that the suspension would force the supplier to close and file bankruptcy, and doing so in the midst of the COVID-19 epidemic jeopardized the supplier's patients and was a danger to their life and health. [4] *Id*.

H. CMS Concludes No Risk to Patients

Shortly thereafter, on September 9, 2020, CMS issued a reply that the patients would "not be irreparably harmed and/or adversely impacted by the continued suspension," essentially because there are other Medicare ambulance suppliers. Exhibit 1, ¶ 14, Ex. C. Defendant continued the suspension action and Plaintiff had no right to an administrative appeal or right to a hear to contest this determination. *Id*.

I. Irreparable Harm to Plaintiff Ambulance Supplier

Acute Care is struggling to survive financially as it continues to provide ambulance services to its very sick patients during the COVID-19 emergency, and with the unique challenges faced in transporting patients in a coronavirus "hot spot." Exhibit 1, ¶ 17. The impact of the

[4] HHS may suspend Medicare payments where there is a "credible allegation of fraud" against the supplier, *unless* there is good cause *not* to suspend payments. 42 C.F.R. § 405.371(a)(2). The regulation provides that that good cause may exist not to suspend a supplier's payments if, among other things, it is determined that beneficiary access to services would be so "jeopardized by a payment suspension," *in whole or in part*, as to cause a "danger to life or health." 42 C.F.R. § 405.371(b)(1)(ii). The government's contention that there are other ambulance suppliers glosses over the stress being placed upon medical transport industry due to COVID-19. Clearly, the application of this exception focuses on the impact of suspension as it relates to the delivery of services by a particular supplier, and not whether services otherwise exist in the healthcare community at large.

Medicare payment suspension threatens to force Acute Care's closure and filing of bankruptcy. The provider derives approximately 90% of its revenue from Medicare, and revenues from the federal program are critical to the survival of the ambulance supplier. Because the supplier is not being paid for medical transports it provides to Medicare beneficiaries, it will soon be compelled to terminate its employees as well as cease operations. *Id*.

If Acute Care is forced to close, patients will have to obtain their medical transports elsewhere. Exhibit 1, ¶ 18. This will cause our patients to obtain ambulance services from other suppliers in the midst of the pandemic when the availability of arranging for such transports is severely limited by COVID-19, and many of these patients may be unable to access essential healthcare under the federal Medicare program. *Id*.

CMS has imposed the suspension even though its impact will force Acute Care's closure and despite the fact it jeopardizes the health and safety of the provider's patients as well as their access to essential healthcare services under the Medicare program. Exhibit 1, ¶ 19. During the current healthcare crisis, these patients may only be able to access essential healthcare through Plaintiff's ambulance supplier. It is feared that the ambulance company will not be able to continue servicing patients without receiving payment for Medicare services much longer, perhaps less than a month, unless Acute Care obtains the emergency relief it seeks and obtains an injunction against the Medicare payment suspension. *Id*.

J. Jeopardy to Health and Safety of Plaintiff's Patients

If Acute Care is forced to close, Plaintiff's patients will have to obtain their ambulance services elsewhere. In the *Declaration Under Penalty of Perjury of Jan Spears*, a healthcare consultant with over 35 years' experience in Medicare home care operations, she explained that because approximately 90% of Plaintiff's revenues are from Medicare, it was clear the provider

cannot sustain operations, and the impact of the suspension threatens to force its closure. Exhibit 2, ¶ 2, 3 and 14, Ex. A.

According to Ms. Spears, CMS should have found good cause exists not to suspend Plaintiff's Medicare payments because beneficiary access to items or services would be so jeopardized by a payment suspension as to cause a danger to life or health. Exhibit 2, ¶ 15. The federal regulation at 42 C.F.R. § 405.371(b)(1)(ii) provides that CMS may find that good cause exists not to suspends payments or not to continue to suspend payments to an entity against which there is a credible allegation of fraud if it is "determined that beneficiary access to items or services would be so jeopardized because such a payment suspension in whole or in part as to cause danger to life or health." *Id*. She pointed out that the COVID-19 pandemic and the surge of confirmed coronavirus cases was having an overwhelming impact on America's healthcare system, including Texas ambulance suppliers in the Rio Grande Valley. *Id*., at ¶ 16.

The heavy burden on ambulance suppliers poses a significant threat to patients who must have life-saving dialysis treatment if medical transports are interrupted during the pandemic. Exhibit 2, ¶ 11. Suspending Medicare payments to any ambulance supplier limits the industry in totality from meeting the needs of the most vulnerable at an extreme period of crisis. *Id.*

Ms. Spears opined that CMS has imposed the suspension even though its impact will force Acute Care's closure and despite the fact it jeopardizes the health and safety of patients of the provider and their access to essential healthcare services. Exhibit 2, ¶ 19. She also expressed a concern for those patients of the ambulance supplier who may be unable to receive needed dialysis services at a time when ambulance suppliers are overburdened and limited in availability. *Id*., at 19.

K. Federal Lawsuit Seeking Injunctive Relief

In early-August, 2020, Acute Care filed suit against HHS alleging procedural Due Process and *ultra vires* claims. Exhibit 1, ¶ 15, Ex. D. The Complaint alleged that its Due Process and

ultra vires claims are collateral to the administrative process, invoking *Mathews v. Eldridge*, 424 U.S. 319, 326-32 (1976). Additionally, the claims rely on *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 19 (2000), and assert that jurisdiction lies because §405 "would not simply channel review through the agency, but would mean no review at all." In such situation jurisdiction is available under 28 U.S.C. § 1331. *Id*. Thereafter, on or about October 1, 2020, we filed this Motion for Preliminary Injunction with the Court. *Id*.

APPLICABLE MEDICARE LAWS

A. The Medicare Program

As part of the Social Security Amendments of 1965, Congress established the Medicare program: a national health insurance plan to cover the cost of medical care for the elderly and disabled. *See* 42 U.S.C. § 1395 *et seq*. Officially known as "Health Insurance Benefits for the Aged and Disabled," it provides basic protection against the costs of inpatient hospital and other institutional provider care. It also covers the costs of physician and other healthcare practitioner services and items not covered under the basic program. In 1997, beneficiaries were extended the option of choosing a managed care plan. More recently, in 2006, the program was expanded further to include a prescription drug benefit.

B. Ambulance Services

Ambulance services are covered by Medicare when the use of other methods of transportation is contraindicated. Essentially, this requires that the ambulance supplier show that patients' health would be jeopardized by use of any other mode of transportation. Coverage requires that the following conditions must be met: the supplier meets the requirements of 42 C.F.R. § 410.41; the services meet the medical necessity and origin and destinations requirements of 42 C.F.R § 410.40; and Medicare Part A payment is not made directly or indirectly for the

services. Typically, Medicare cover emergency ambulance transportation when a patient experience sudden medical emergency and it endangers his or her health. It also covers nonemergency transportation when medically necessary, and the patient has a written order his or her physician that ambulance transportation is medically necessary.[5]

For nonemergency ambulance transportation, medical necessity is satisfied if either: the beneficiary is bed-confined and it is documented that other methods of transportation are contraindicated; or the beneficiary's medical condition, regardless of bed-confinement, is such that ambulance transportation is medically required. To be bed-confined, the beneficiary must be unable to get up from bed without assistance; ambulate; or sit in a chair of wheelchair. 42 C.F.R. § 410.40(d).

Medicare covers the following levels of ambulance services:

- Basic life support;
- Advanced life support;
- Paramedic ALS intercept;
- Specialty care transport;
- Fixed wing transport; and
- Rotary wing transport.

42 C.F.R. § 410.40(b).

Medicare covers the following ambulance transportation:

- From any point of origin to the nearest hospital, critical access hospital, or skilled nursing facility that is capable of furnishing the required level and type of care for the beneficiary's illness or injury;

- From a hospital, critical access hospital, or skilled nursing facility to the beneficiary's home;

- From a skilled nursing facility (SNF) to the nearest supplier of medically necessary services not available at the SNF where the beneficiary is a resident, including the return trip; and

[5] To satisfy the medical necessity requirement, the beneficiary's condition must require both the ambulance transportation itself and the level of service provided. *See* 42 C.F.R. § 410.40(d).

- For a beneficiary who is receiving renal dialysis for treatment of end-stage renal disease, from the beneficiary's home to the nearest facility that furnishes renal dialysis, including the return trip.

42 C.F.R. § 410.40(e).

C. Ambulance Reimbursement

Ambulance services are reimbursed under a fee schedule payments system. The fee schedule payment equals a base rated for the levels of service plus a separate payment for mileage to the nearest appropriate facility and applicable adjustment factors. 42 U.S.C. § 1395m(l); 42 C.F.R. §§ 414.601 and 414.610(a).

D. Payment and Audit Functions

Medicare's payment and audit functions are performed by various federal contractors. For instance, the payment of ambulance service claims at issue in this case was made by Palmetto GBA, LLC. Various other contractors, like Qlarant, a Unified Program Integrity Contractor ("UPIC"), investigate instances of suspected fraud, waste, and abuse as well as identify any improper payments that are to be collected by Administrative Contractors.

E. Appeal Process

Ambulance suppliers participating in the Medicare program are entitled to appeal the initial determination. *See* 42 U.S.C. § 1395ff. Federal regulations establish an elaborate administrative appeal process to review the adverse action. *See* 42 C.F.R. Subpart I – Determination, Redeterminations, and Appeals Under Original Medicare. A provider dissatisfied with an initial determination may request a Redetermination by a contractor in accordance with 42 C.F.R. §§ 405.940-405.958. The Redetermination must be issued within sixty (60) calendar days. If a provider is dissatisfied with a Redetermination decision, it may request a Reconsideration by a Qualified Independent Contractor ("QIC") in accordance with 42 C.F.R. §§ 405.960-405.986.

The Reconsideration must be issued within sixty (60) calendar days. In the event the provider is dissatisfied with the Reconsideration decision, it may request an ALJ hearing in accordance with 42 C.F.R. §§ 405.1000-405.1054. The ALJ must issue a decision within ninety (90) calendar days. The provider may request review of the ALJ's decision by the Medicare Appeals Council in accordance with 42 C.F.R. §§ 405.1100-405.1140. The Council must issue a decision within ninety (90) calendar days. The Council's decision is the final agency action, and it is subject to judicial review. *See* 42 U.S.C. § 1395ff; 42 C.F.R. §§ 405.1130, 405.1132, 405.1134; *see also* 42 U.S.C. § 405(g).

F. Suspension of Medicare Payments

Medicare payments to ambulance suppliers may be suspended, in whole or in part, by CMS or its contractors, if there is "reliable information that an overpayment exists." 42 C.F.R. § 405.371(a)(1). In cases of suspected fraud, CMS or its contractors may suspend Medicare payments where there is a "credible allegation of fraud" against the supplier, unless there is good cause not to suspend payments. 42 C.F.R. § 405.371(a)(2). CMS may find that good cause exists not to suspend a supplier's payments where, among other things, it is determined that beneficiary access to services would be so "jeopardized by a payment suspension" as to cause a "danger to life or health." 42 C.F.R. § 405.371(b)(ii).

Every 180 days after the initiation of a suspension of payments based on a credible allegation of fraud, CMS will evaluate whether there is good cause to extend the suspension. 42 C.F.R. § 405.371(b)(2). Good cause to not continue a suspension is deemed to exist if it has been in effect for 18 months and there has not been a resolution of the investigation. 42 C.F.R. § 405.371(b)(3). However, the suspension can be continued indefinitely if the case has been referred to OIG for enforcement action or DOJ requests that it be continued based on the ongoing

investigation and anticipated filing of criminal or civil action or both. 42 C.F.R. §§ 405.371(b)(3)(i), (ii).

G. Rebuttal Statement

A supplier whose payments are suspended without notice, as in this case, is given by the Medicare contractor an opportunity to submit a rebuttal statement as to why the suspensions should be removed. 42 C.F.R. § 405.372(b)(2). *See also* 42 C.F.R. § 405.374. When a rebuttal statement is submitted, CMS, or its contractor, must within 15 days from the date of its receipt must issue written notice the determination. The rebuttal determination is not an appealable decision. 42 C.F.R. §§ 405.375(a)-(c). [6]

ARGUMENT

Plaintiff seeks to temporarily enjoin a Medicare payment suspension that will otherwise force the ambulance supplier's closure, and that jeopardizes the health and safety of its patients. HHS violates Due Process of Law and the Fifth Amendment of the U.S. Constitution by imposing a Medicare payment suspension that confiscates all earned Medicare payment but provides no appeal or right to a hearing to challenge the sanction. Accordingly, Plaintiff seeks to enjoin the suspension before a hearing, which is plainly collateral to the result of the hearing. [7]

A. Plaintiff has a Property Interest in Earned Medicare Payments

The questions presented in this case are of critical importance to healthcare providers participating the Medicare program. At issue are the payments earned by the supplier that has delivered ambulance services to beneficiaries and the administrative process extended to them to challenge HHS's Medicare payment suspension. The Fifth Circuit's decision in *Family*

[6] The suspension is not considered an "initial determination" and no appeal rights, including right to ALJ hearing, are extended to a provider to contest the adverse action.
[7] *See Family Rehabilitation, Inc. v. Azar*, 886 F.3d at 501-05.

Rehabilitation and its progeny hold that providers have a protected property interest in earned Medicare payments that are suspended and withheld to be applied towards Medicare overpayments. *See Family Rehabilitation, Inc. v. Azar*, 886 F.3d 496 (5th Cir. 2018) (District court has jurisdiction under collateral-claim exception to hear supplier's procedural due process and *ultra vires* claims); *Family Rehabilitation, Inc. v. Azar*, No. 3:17-CV-3008-K, 2020 WL 230615 (N.D. Tex. Jan. 15, 2020), *Med-Cert Home Health Care, LLC v. Azar*, 365 F.Supp.3d 742 (N.D. Tex. Feb. 4 2019), *Adams EMS, Inc. v. Azar*, No. H-18-1443, 2018 WL 5264244 (S.D. Tex. Oct. 23, 2018), and *Home Health Innovations, Inc. v. Azar*, No. 5:18-CV-00601, 2018 WL 8809231 (W.D. Tex. June 18, 2018). When addressing the government's contention that healthcare providers have no property interest in Medicare payments, Judge Kinkeade asserted the "position was so ludicrous as to be specious." *Family Rehabilitation*, 2020 WL 230615 at *5. Nonetheless, HHS imposes a suspension without making available to the supplier an appeal or right to a hearing to challenge the action. *See* 42 C.F.R. §§ 405.372 and 405.375(c). Obviously, there is a high risk of deprivation when no appeal or hearing is available to challenge the suspension. This case addresses the serious legal question of whether a Medicare certified ambulance supplier has a property interest in earned Medicare payments *and* if there is a high risk of deprivation when an appeal or hearing is not available to challenge the suspension action.

B. Acute Care is Entitled to Issuance of a Preliminary Injunction

Violation of Acute Care's Due Process rights is indisputably clear when the supplier will be forced to shut down and file bankruptcy if injunctive relief is not made available. To be entitled to a preliminary injunction, a movant must show (1) a likelihood of success on the merits; (2) a substantial threat of irreparable injury to Plaintiff if an injunction is not granted; (3) that the threatened injury to Plaintiff outweighs the threatened harm the injunction may do to Defendant;

and (4) that granting the preliminary injunction will not disserve the public interest. *Canal Authority of State of Fla. v. Callaway*, 489 F.2d 567, 572 (5th Cir. 1974). Thus, a preliminary injunction may be issued in the discretion of the Court to protect Plaintiff from irreparable injury and to preserve the Court's power to render a meaningful decision after a trial on the merits. *Id*. The most compelling reason in favor of granting a preliminary injunction is the need to prevent the judicial process from being rendered futile by Defendant's action. *Id*., at 573. While it is often loosely stated that the purpose of a preliminary injunction is to preserve the *status quo*, it has long been recognized that there is no particular magic in the phrase "*status quo*." The focus of injunctive relief is on the prevention of injury by a proper order, not merely on preservation of the *status quo*. If the currently existing *status quo* itself is causing one party irreparable injury, it is necessary to alter the situation so as to prevent the injury, either by returning to the last uncontested *states quo* between the parties or by allowing the parties to take proposed action that will minimize the irreparable injury. *Id*., at 576. Accordingly, this Court should order HHS to cease its suspension of Plaintiff's payments and return those being withheld to the supplier. As shown below, Acute Care meets all of these factors and is entitled to an injunction.

1. Plaintiff will Likely Succeed on the Merits of its Due Process Claim

Acute Care is likely to prevail on its underlying procedural due process claim. *See Canal Authority.* 489 F.2d at 572 (factor one). "Procedural due process protects against governmental deprivation of a liberty or property interest." *Mathews v. Eldridge*, 424 U.S. at 332. When analyzing whether a party's procedural Due Process rights have been violated, courts weigh three factors:

> First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards, and finally, the Government's

> interest, including the function involved and the fiscal administrative burdens that the additional or substitute procedural requirements would entail.

Id. at 335. (emphasis added).

a. First *Mathews* Factor

Under the first *Mathews* factor, the Court determines whether there is a private interest that will be affected by the government's action. *See Mathews v. Eldridge*, 424 U.S. at 335. The evolving precedent in this jurisdiction holds that Medicare suppliers have a legitimate claim of entitlement to payment for services that are covered under the Medicare Act and actually rendered. *See, e.g., Family Rehabilitation*, No. 3:17-CV-3008-K, 2020 WL 230615 at *5 (N.D. Tex. 2020). To have a property interest in a benefit, a person clearly must have more than an abstract need or desire for it. He must have more than a unilateral expectation of it. He must instead have a "legitimate claim of entitlement to it*." Board of Regents of State Colleges v. Roth*, 408 U.S. 564, 577 (1972). Thus, property interests are created and their dimensions defined by existing rules or understandings that stem from an independent source such as state law rules or understandings that secure certain benefits and support claims of entitlement to those benefits. *Pers. Care Prods., Inc. v. Hawkins*, 635 F.3d 155, 158 (5th Cir. 2011) (citing *Roth*, 408 U.S. at 577).

In *Med-Cert Home Care, LLC v. Azar*, the Honorable Judge Fish presiding in the Northern District of Texas analyzed this issue and found that "precedent makes clear that [the provider] has a valid property interest in receiving Medicare payments for services rendered." 365 F. Supp. 3d 742, 751 (N.D. Tex. 2019); *see Family Rehabilitation*, 2020 WL 230615 at *4 (concluding a Medicare-certified home health agency whose Medicare payments were being withheld had a property interest in the Medicare payments for services rendered); *Adams EMS, Inc. v. Azar*, No.

H-18-1443, 2018 WL 5264244, at *10 (S.D. Tex. Oct. 23, 2018) (Ambulance supplier had "a property interest in receiving and retaining the Medicare payments it has earned."). Indeed, district courts throughout the Fifth Circuit have found that healthcare providers and suppliers do, in fact, have a valid property interest in earned Medicare payments. *See also Home Health Innovations, Inc. v. Azar*, No. 5:18-CV-00601, 2018 WL 8809231 (W.D. Tex. June 18, 2018) (The Court granted the TRO "finding the Appellant had met its burden of persuasion on all four factors").

HHS has consistently argued in the *Family Rehab* line of cases that suppliers have no property interest.[8] In fact, early cases are at odds with recently issued precedent holding that providers have a property interest in earned Medicare payments. Indeed, the Fifth Circuit has issued prior decision that run contrary to *Family Rehabilitation* and its progeny. For example, in *Peterson v. Weinberger*, 508 F.2d 45 (5th Cir. 1975), the Court relied on *Hilburn v. Butz*, 463 F.2d 127 (5th Cir. 1972) to conclude there was no denial of Due Process. There the Court distinguished the applicability of *Goldberg v. Kelly*, 397 U.S. 254 (1970), which was based on judicial notice of the fact that welfare recipients as a class would be deprived of their very means of existence while awaiting an outcome of a post-termination hearing. Thus, preventing them from seeking redress under the welfare program. In *Peterson*, the Court reasoned that the plaintiff had failed to show the provider had incurred any "dire consequences" due to the suspension. Obviously, this case is very different because the suspension will result in irreparable harm to the supplier by forcing its closure and filing of bankruptcy.

[8] HHS conceded in oral argument in *Sahara* that the provider actually does have a property interest in earned Medicare payments. *Sahara Health Care Inc., v. Azar II,* No. 18-41120 (5th. Cir. Nov. 7, 2019) (Oral Argument at 21:25).

Likewise, in the recently decided *True Health Diagnostics, LLC v. Azar*, 392 F.Supp.3d 666 (E.D. Tex. 2019), the trial court found no Due Process violation due to suspension. The *True Health* Court found that the diagnostic laboratory failed to show it could not obtain full relief at a post-deprivation hearing. The Court also pointed out that the plaintiff sought *permanent* injunctive relief to stop the suspension of claims that were part of a previous suspension action, and it did not show that its claims are wholly collateral. Acute Care is faced with shutdown and bankruptcy as result of the suspension. But the supplier only seeks *temporary* injunctive relief, i.e., until the COVID-19 emergency is lifted or until an appeal or hearing is provided to challenge the suspension action. As in *Family Rehabilitation*, Plaintiff seeks only temporary relief from the suspension until a hearing, which is quite different from a permanent reinstatement of benefits. 886 F.3d at 503-94. It is plainly collateral to the result of the hearing. *Id*.

When addressing the government's contention that healthcare providers have no property interest in Medicare payments, Judge Kinkeade asserted the "position was so ludicrous as to be specious." *Family Rehabilitation*, 2020 WL 230615 at *5. He stated, "[i]f there were no recognized property interest, they would be expected to treat every patient as a charity case where reimbursement would just be a nice bonus." *Id*. He concluded that "Medicare suppliers would not provide service to Medicare patients without the reasonable expectation of payment, [and] the Medicare statute constitutes an 'independent source' that 'support[s] claims of entitlement filed by Medicare suppliers.*" Id.* Because "the Medicare statute outlines a program for reimbursement, a supplier who renders service to Medicare patients has more than a unilateral expectation." *Id.* Thus, Acute Care has a substantial interest in the receipt of Medicare payments for covered services it has rendered that ultimately affects its private interest in the survival of the business." *Id*., at *4.

Clearly, Plaintiff has a property interest in suspended Medicare payments under 42 C.F.R. § 405.371(a)(2).

Importantly, the suspension withholds from the supplier *approved* Medicare payments that are "applied to reduce or liquidate any overpayment." 42 C.F.R. § 405.372(e). *See also* 42 C.F.R. § 405.370 (definition of "suspension of payment"). This is distinguishable from the situation where a State imposes a "payment hold" on current claims because of "prima facie evidence of fraud" on past claims. *See Pers. Care Prods., Inc. v. Hawkins*, 635 F.3d 155, 157 (5th Cir. 2011). HHS contends *Personal Care Products* bars injunctive relief and has argued that the supplier has no property interest in its earned Medicare payments because of an "allegation of fraud" (Doc. 00515516371, at 15-17). Under a Medicaid payment hold, the state inspector general may impose a "payment hold" on payments of "future claims" submitted for reimbursement. 1 Tex. Admin. Code § 371.1703. In other words, it is a hold on payment of future claims when there is "prima facie evidence" of fraud – the future payments are tainted. Thus, the Fifth Circuit held in *Personal Care Products* that the Commission's investigation of the supplier found prima facie evidence of fraud, and "Texas law" gave the supplier "no claim of entitlement" to its future Medicaid reimbursements. *Id*., at 159. Of course, no person has a legitimate claim of entitlement to property that is not theirs.

However, a Medicare payment suspension is very different because the government is actually withholding "approved Medicare payments." 42 C.F.R. § 405.370(a) (definition of suspension). These payments are not tainted by fraud. Suspension is akin to seizing the supplier's money owed for services rendered. Obviously, if these monies were paid into a bank account, the supplier would have a protected property interest. Indeed, no one would dispute that suppliers have a property interest in their bank accounts that requires some measure of protection

under the due process clause. *See, e.g., Finberg v. Sullivan*, 634 F.2d 50 (3rd Cir. 1980). Clearly, the result should be the same with respect to suspended payments and the money paid for services rendered. Governmental deprivation of such an interest must be accompanied by minimum procedural safeguards, including some form of notice and a hearing. *See Arnett v. Kennedy*, 416 U.S. 134, 164 (1974) (Powell, J., concurring). One can only hope our constitutional rights are not so tenuous as to be lost forever because of a mere allegation.

b. Second *Mathews* Factor

Under the second *Mathews* factor, the Court determines whether the procedures used protect the private interest. *Mathews v. Eldridge*, 424 U.S. at 335. *See also Family Rehabilitation*, *See,* 2020 WL 230615 at *8. Not only has the supplier not been extended an administrative appeal or otherwise provided a hearing to challenge the suspension, Plaintiff's Medicare payments are suspended for an *indefinite* period because there is no established time frame for resolving the investigation.[9] Judge Kinkeade recognized that a hearing is critical to "decreasing the risk of erroneous deprivation" even in a multi-state review process. *See Family Rehabilitation*, 2020 WL 230615 at *9. Thus, it cannot be disputed there is a high risk that Plaintiff will be erroneously deprived of its property interest in Medicare payments suspended in accordance with 42 C.F.R. § 405.371(a).

Moreover, the opportunity for rebuttal does not satisfy the requirements for "some kind of a hearing." *See* 42 C.F.R. § 405.372(b). *See Wolff v. McDonnell*, 418, U.S. 539, 557-58 (1974). While the regulations instruct suppliers have an opportunity for rebuttal and that they may submit a "statement (to include any pertinent information) as to why" the suspension

[9] Under the regulations, good cause not to continue to suspend payments is deemed to exist if a payment suspension has been in effect for 18 months and there has not been a resolution of the investigation, but HHS may extend the suspension beyond that point when the case has been referred to and sanctions are being considered by the OIG *or* DOJ has an ongoing investigation. *See* 42 C.F.R. §§ 405.371(b)(3)(i) and 405.371(b)(3)(ii).

should not be put into effect, *see* 42 C.F.R. § 405.374(b), they also are informed the determination is "not an initial determination and not appealable." *See* 42 C.F.R. § 405.375(c). The rebuttal process is nothing more than a unilateral review of the suspension. Judge Friendly's influential article "Some Kind of Hearing," created a list of basic due process rights. *See* Henry J. Friendly, *Some Kind of Hearing*, 123 U. Pa. L. Rev. 1267 (1975). The opportunity for rebuttal fails to satisfy *almost all* of these. The rebuttal process is not before an unbiased tribunal; there is no right to know the opposing evidence; there is no right to cross examine; the decision is not based only on the evidence presented; and the decision is not reviewable. In other words, the supplier is simply given an opportunity to complain, but it does so to CMS who imposed the adverse action, and though the agency considers the rebuttal, it does so absent any standard of review or void of any of the earmarks of Due Process.

While HHS may argue a hearing is made available to the supplier, it only is offered *after* an overpayment has been determined. *See* 42 U.S.C. § 1395ff; 42 C.F.R. Subpart I. The supplier must wait until the completion of the investigation, which lasts for an *indefinite* period of time, and the issuance of an overpayment determination, that is, if one *ever* is issued. It is not uncommon for such investigations to take more than a year or longer to complete before the overpayment determination is made. Only then can the supplier pursue an administrative appeal of *the overpayment*. As this Court is well aware, the provider may then have to wait for as long as five years for a hearing, and while the government is recouping its Medicare payments. *See Family Rehab*., 886 F.3d at 500. Under the agency's scheme, the Medicare payment suspension essentially escapes *any* meaningful review other than the unilateral review of the rebuttal. Clearly, there is a high risk of deprivation under the rebuttal process used by HHS that is void of the most basic Due Process rights as to the suspension of Plaintiff's Medicare earned payments.

c. Third *Mathews* Factor

The third *Mathews* factor weighs the fiscal and administrative burdens that the additional or substitute procedural requirement would entail. *See Mathews v. Eldridge*, 424 U.S.. at 335. HHS cannot hide behind the contention it has an interest in protecting the Medicare Trust Funds and administering it efficiently. While the government may contend it has a right to suspend payments because of a "credible allegation of fraud," it does not have a right to make such allegations and deny the provider Due Process and a hearing to challenge the adverse action. Because the suspension would force the provider's closure prior to a hearing, Plaintiff's interest is greater than the government's interest in protecting the Medicare Trust Fund and administering it efficiently. Indeed, the quandary that HHS finds itself arises from *inefficient* administration. *See Family Rehab*., 2020 WL 230615, at *10 (Because recoupment and collection of an alleged overpayment would shut down the supplier prior to a hearing). Clearly, HHS's hypothetical risk of loss to Plaintiff does not outweigh Acute Care's ongoing deprivation of its property interest without Due Process. *See Family, Rehab*., 2020 WL 230615, at *11 (Going out of business outweighs the burden of delayed recoupment).

Likewise, the patients at Acute Care have a constitutional Due Process right (consistent with principles of equal protection) to access safe and reliable services under the federal Medicare program. [10] *See Bolling v. Sharpe*, 347 U.S. 497, 499 (1954) (But the concepts of equal protection and due process, both stemming from our American ideal of fairness, are not

[10] A patient cannot secure Medicare ambulance services without the aid of a certified supplier, and a Medicare beneficiary cannot secure such transports without the supplier being paid by the Medicare program. Clearly, a patient's right to access safe and reliable services under the federal Medicare program is at stake here. Moreover, the patient's constitutional right to access is one in which the supplier is intimately involved. *See Singleton v. Wulff*, 428 U.S. 106 (1976). Therefore, Plaintiff is uniquely qualified to litigate the constitutionality of the government's interference with, or discrimination against, such access, and the supplier appropriately asserts the rights of beneficiaries against governmental interference with access to ambulance services.

mutually exclusive. The equal protection of the laws is a more explicit safeguard of prohibited unfairness than due process of law, and, therefore, we do not imply that the two are always interchangeable phrases. But, as this Court has recognized, discrimination may be so unjustifiable as to be violative of due process). In fact, it has been a longstanding core value of Medicare that the program should provide equal access to appropriate and high-quality health services for all beneficiaries, including those with chronic, long-term, and mental health conditions.[11] Indeed, the Supreme Court observed many years ago that "medical care is as much a basic necessity of life to an indigent as welfare assistance." *See Mem. Hosp. v. Maricopa Co.*, 415 U.S. 250, 259 (1974). HHS discriminates against the class of Medicare beneficiaries entitled to medically necessary ambulance services by imposing suspension under circumstances that place in jeopardy their health and safety and will deny to them access to essential healthcare. *Id*. *See* also *Spears Declaration*, ¶¶ 15-18. Acute Care has shown the violation of its rights is indisputably clear.

2. There is a Substantial Threat of Irreparable Injury to Plaintiff if an Injunction is Not Granted

Imminent and irreparable injury will occur if this Court does not grant Plaintiff's motion for preliminary injunction and order the requisite injunctive relief. *See Canal Authority.* 489 F.2d at 572 (factor two). To establish irreparable injury, Plaintiff must establish "a significant threat of injury from the impending action, that the injury is imminent, and that money damages would not fully repair the harm." *Family Rehabilitation, Inc. v. Azar*, No. 3:17-CV-3008-K, 2018 WL 3155911, at *6 (N.D. Tex. June 28, 2018) (quotation omitted). The suspension will force the provider to shut down its business and file bankruptcy. *See Rojas Declaration*, Exhibit 1, ¶¶ 17-

[11] *See* www.medicareadvocacy.org/medicare-info/medicare-and-health-care-reform/

19. Going out of business is an irreparable injury. *Family Rehab*., 886 F.3d. at 504. ("The combined threats of going out business and disruption to Medicare patients are sufficient for irreparable injury."). Likewise, the suspension jeopardizes the patients' access to ambulance services provided by Plaintiff, and doing so in the midst of the COVID-19 emergency poses a danger to their life or health. *See Spears Declaration*, Exhibit 2, ¶¶ 15-18. Clearly, there is irreparable injury if the injunction is denied.

3. The Balancing of Hardships Sharply Favors Plaintiff

The threatened injury faced by Acute Care outweighs the harm that would be sustained by HHS if the injunction is not granted. *See Canal Authority.* 489 F.2d at 572 (factor three). Without injunctive relief, Plaintiff will be forced to shutter its doors and close down its business, and the Medicare beneficiaries relying on the supplier must seek to obtain essential ambulance services elsewhere during the COVID-19 emergency when access to such services is uncertain during this crisis. On the other hand, HHS will not suffer harm from granting the injunctive relief sought because the government will *always* have the opportunity to later suspend or otherwise collect Medicare payments for services *if an overpayment is ultimately determined*. *See Family Rehabilitation*, 2018 WL 3155911, at *7; *see Med-Cert*, 365 F. Supp. 3d at 757. The government will only be required to do what it is otherwise obligated to do under law, pay for the current claims of Medicare beneficiaries. Indeed, the *only* harm posed here is to Acute Care as it will go out of business and file bankruptcy if the injunction is denied. This harm will have a cascading effect. Employees will lose their jobs. Medicare beneficiaries that rely on the provider will have their essential healthcare services disrupted in the midst of the pandemic.

4. An Injunction is in the Public Interest

Issuance of the injunction would not adversely affect the public interest. *See Canal Authority.* 489 F.2d at 572 (factor four). The quality of the ambulance services provided by Plaintiff is not at issue, only the reimbursement for these services. No public interest would be adversely affected by granting injunctive relief. If anything, the public would benefit from continued access to the provider's services. *See Family Rehabilitation*, 2020 WL 230615, at *11; *Med-Cert*, 365 F.Supp. 3d at 757 (Not disserve the public interest by conflicting with Congress' statutory scheme).[12] Clearly, granting the injunction does not disserve the public interest.

Without doubt, the latter three factors are heavily tilted in Acute Care's favor, and especially in light of *Family Rehabilitation*, *Med-Cert*, *Adams EMS*, and *Home Health Innovations,* precedent where trial courts have considered essentially the same issues and held in favor of the supplier. Plaintiff has established there is irreparable injury if the injunction is denied. *See* Part B, 2. It has established that the injunction would not substantially harm the government. *See* Part B, 3. Plaintiff has also established that granting the injunction does not disserve the public interest. *See* Part B, 4. Thus, Acute Care has shown that the balance of the equities weighs heavily in favor of granting the injunction. Where, as here, the denial of an injunction "will utterly destroy the *status quo*," irreparably harming the supplier, but granting of the injunction will cause relatively slight harm to the government, Plaintiff need not show an absolute probability of success in order to be entitled to an injunction. *See Ruiz v. Estelle*, 650 F.2d 555, 565 (5th Cir. 1981) (citing *Providence Journal Co. v. Federal Bureau of Investigation*,

[12] Plaintiff should not be required to post a bond because HHS is obligated to pay for the ambulance services of the Medicare beneficiaries on service at the supplier. *See Family Rehab*., 2018 WL 3155911, at *7 (In its discretion, the Court waived the bond requirement upon issuance of preliminary injunction).

595 F.2d 889, 890 (1st Cir. 1979)). *See also Washington Metropolitan Area Transit Commission v. Holiday Tours, Inc.*, 559 F.2d 841, 843 (D.C. Cir. 1997). Clearly, balancing of the equities strongly favors an injunction.

CONCLUSION

For the reasons stated in this application, Acute Care meets all of the requirements for a preliminary injunction in this case, and the public interest is best served by this Court granting the application.

Respectfully submitted,

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/s/ Mark S. Kennedy

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CERTIFICATE OF CONFERENCE

I hereby certify that on October 2, 2020, our office reached out to Counsel for Defendant regarding their Client's opposition to Plaintiff's motion. Counsel for Defendant informed our office that Defendant opposes this motion.

/s/ Mark S. Kennedy

MARK S. KENNEDY

CERTIFICATE OF SERVICE

I hereby certify that on October 2, 2020, an electronic copy of the foregoing motion was filed with the Clerk of the United States District Court for the Southern District of Texas using the CM/EFC filing system and that service will be accomplished using the CM/ECF system.

/s/ Mark S. Kennedy

MARK S. KENNEDY

APPENDIX

Exhibit 1..... Declaration of Juan Carlos Rojas

Exhibit 2..... Declaration of Jan Spears

Exhibit A.....July 24, 2020 Notice of Suspension

Exhibit B..... August 3, 2020 Rebuttal Statement to Qlarant

Exhibit C.....September 9, 2020 CMS Reply

Exhibit D.....Complaint filed by Acute Care

Cases / Other Authorities

Exhibit E..... *Adams EMS, Inc. v. Azar*, No. H-18-1443, 2018 WL 5264244 (S.D. Tex. Oct. 23, 2018)

Exhibit F..... *Family Rehabilitation, Inc. v. Azar*, No. 3:17-CV-3008-K, 2020 WL 230615 (N.D. Tex. Jan. 15, 2020)

Exhibit G.....*Family Rehabilitation, Inc. v. Azar*, No. 3:17-cv-3008-K, 2018 WL 3155911 (N.D. Tex. June 28, 2018)

Exhibit H.....Henry J. Friendly, *Some Kind of Hearing*, 123 U. Pa. L. Rev. 1267 (1975)